Comparison Between EPA Assumptions for Lung Cancer Risk Assessment and the 16 Cities Study Environmental Tobacco Smoke Exposure Data

Comments to the National Toxicology Program's Deliberations on Environmental Tobacco Smoke

December 2, 1998

by
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My name is Roger Jenkins. I have a Ph.D. in Analytical Chemistry. I have been with the Oak Ridge National Laboratory, a Department of Energy research facility in East Tennessee, for 23 years. I am currently the Leader of the Sampling and Analysis Group in the Chemical and Analytical Sciences Division. During most of that time, my studies have involved the characterization and exposure assessment of mainstream and environmental tobacco smoke. These studies have been supported by the National Cancer Institute, the Federal Trade Commission, the Council for Tobacco Research, the University of California - Davis, and the Center for Indoor Air Research. I am here representing my own views, although my appearance here today is supported by the Center for Indoor Air Research, which has sponsored research projects in my Group for the last 10 years.

The purpose of my presentation is to contrast the definitive data from a large study for which I was the Principal Investigator with the assumptions used by the Environmental Protection Agency in its model to estimate relative risk of lung cancer from exposure to environmental tobacco smoke (ETS) and to describe the impact of the data on EPA's risk assessment.

Field work from the so-called 16 Cities Study was conducted in 1993 - 1994. Personal exposure to ETS and other air pollutants was determined for 100 subjects recruited from each of 16 cities scattered across the United States (*see Slide 3*), for a total of 1564 subjects, in both environments at work and away from work. (*Slide 4*). Airborne constituents determined were respirable suspended particulate matter (RSP), ultraviolet absorbing and fluorescing particulate matter (UVPM and FPM), solanesol, scolpoletin, 3-ethenyl pyridine, nicotine, and myosmine (*Slide 5*).

The first example where data from our study differs from assumptions made by the EPA is in the so-called background correction factor, or Z Factor. This is the ratio of exposures encountered by females with smoking spouses to that of those without smoking spouses. The EPA estimated that value of the Z-Factor to by 1.75. Judging from the data in our study (*Slide 6*), the assumed value is clearly lower than that computed from any of the tobacco specific constituents in ETS in our study. For example, for nicotine, Z computed from means was 10.9. The only constituent for which a Z-Factor can be computed which is anything close to that estimate by the EPA is RSP (Z = 2.0), for which there are many other sources in the indoor environment.

The impact on Relative Risk of using a Z-Factor based on definitive exposure data, rather than assumption, is portrayed in Slide 7. Using EPA's own estimation formula, Z Factors in the range determined for this study would dramatically reduce estimated relative risk.

The second example where our findings are in contrast to EPA's assumption is the estimated rate at which females claiming to be lifetime never smokers mis-report their current smoking status. The EPA estimated this rate to be 1.09%. However, based data from our study, we estimate this rate to be ca. 2.95% using a very conservative cut-off level for salivary cotinine. (*Slide 8*). Lower cut-off levels, which are clearly justifiable, result in even higher estimated misclassification rates.

The impact of the difference between EPA's estimate and our experimental data is dramatic, as shown on Slide 9. At a misclassification rate of 2.95%, the lower 90% confidence interval on

relative risk is nearly 1.0. Once the confidence interval includes 1.0, there is no statistically significant elevation in risk.

In conclusion, these findings suggest that key assumptions made by the EPA in its risk assessment of lung cancer due to ETS exposure are not supported by the experimental findings of the largest study of direct personal exposure to ETS ever conducted in the US. Use of definitive data, rather than unsupported assumptions, would act to dramatically lower EPA's estimated relative risk. (*Slide 10*)

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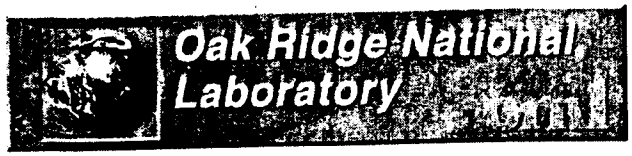
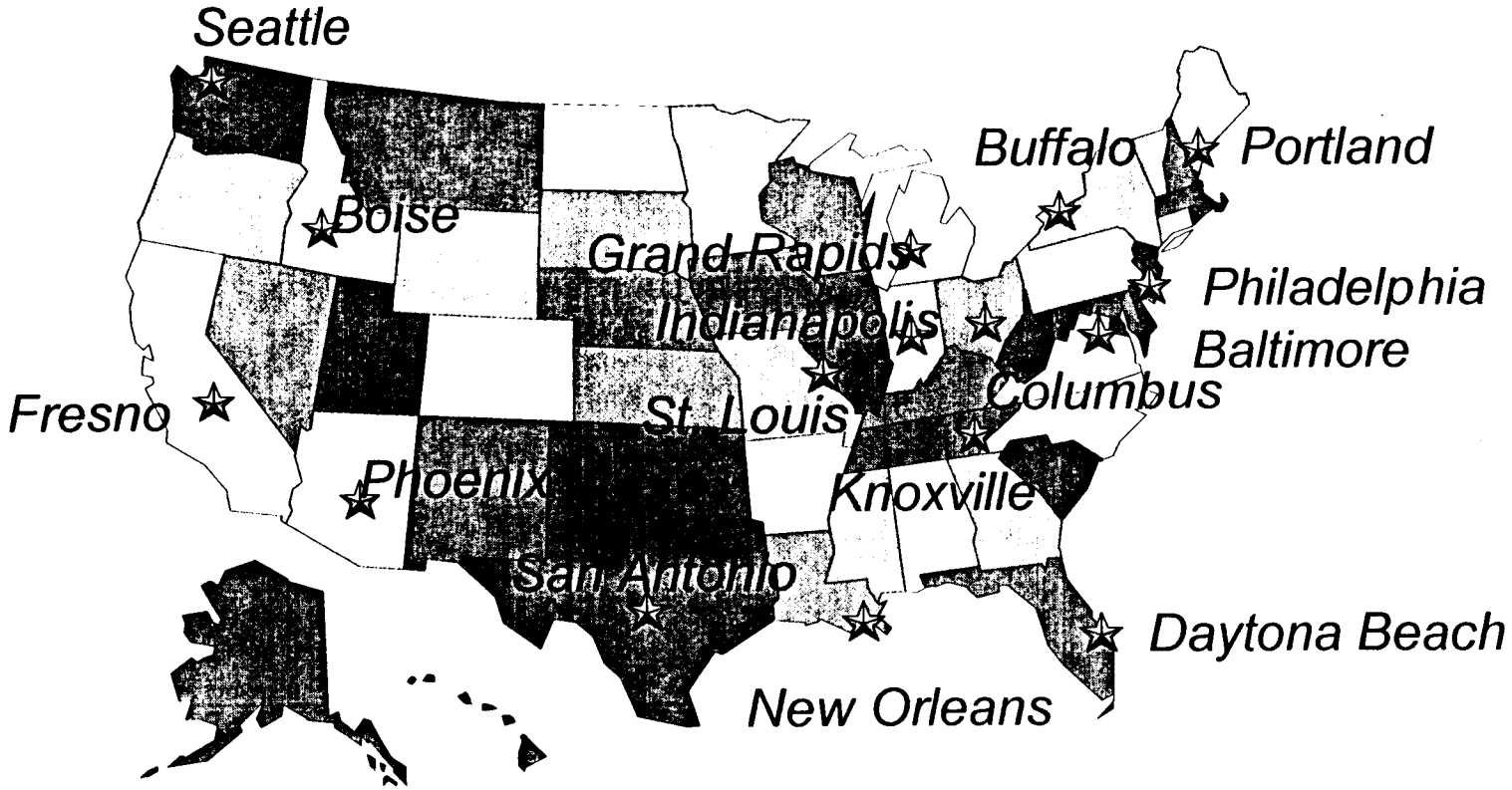


Purpose

- Contrast definitive data from large personal exposure study of ETS with EPA assumptions.
- Describe implications of using definitive data.

16 Urban Areas Distributed Geographically



Sample Collection in the Workplace

Sampling Head

Sampling Pump

Oak Ridge National Laboratory

ETS Components Measured

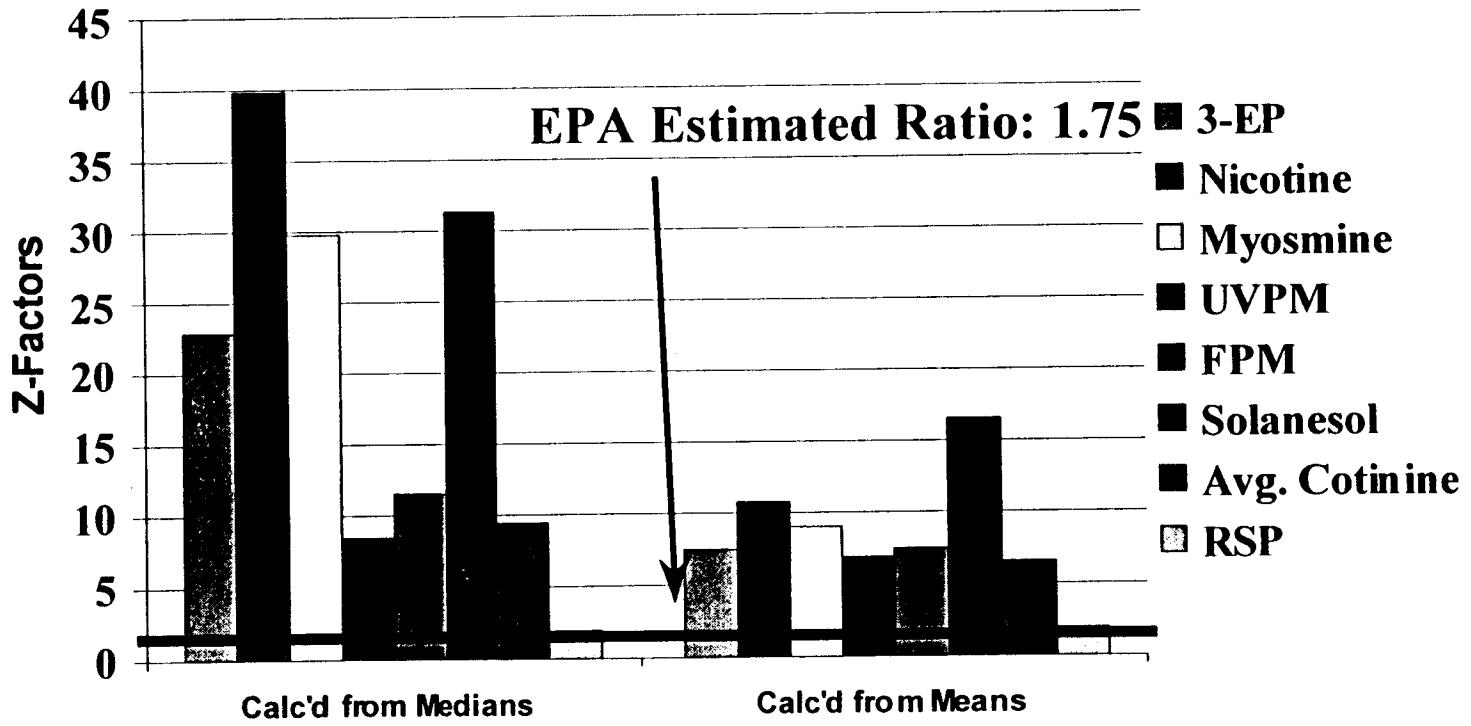
ORNL 16 Cities Exposure Study

- ETS Particle Phase
  - *Respirable suspended particulate matter (RSP)*
  - *UV-absorbing particulate matter (UVPM)*
  - *Fluorescing particulate matter (FPM)*
  - *Solanesol*
  - *Scopoletin*
- ETS Vapor Phase
  - *3-ethenyl pyridine*
  - *Nicotine*
  - *Myosmine*
- Saliva
  - *Cotinine*

Ratios of 24-hr Exposures of Never Smoking Women:

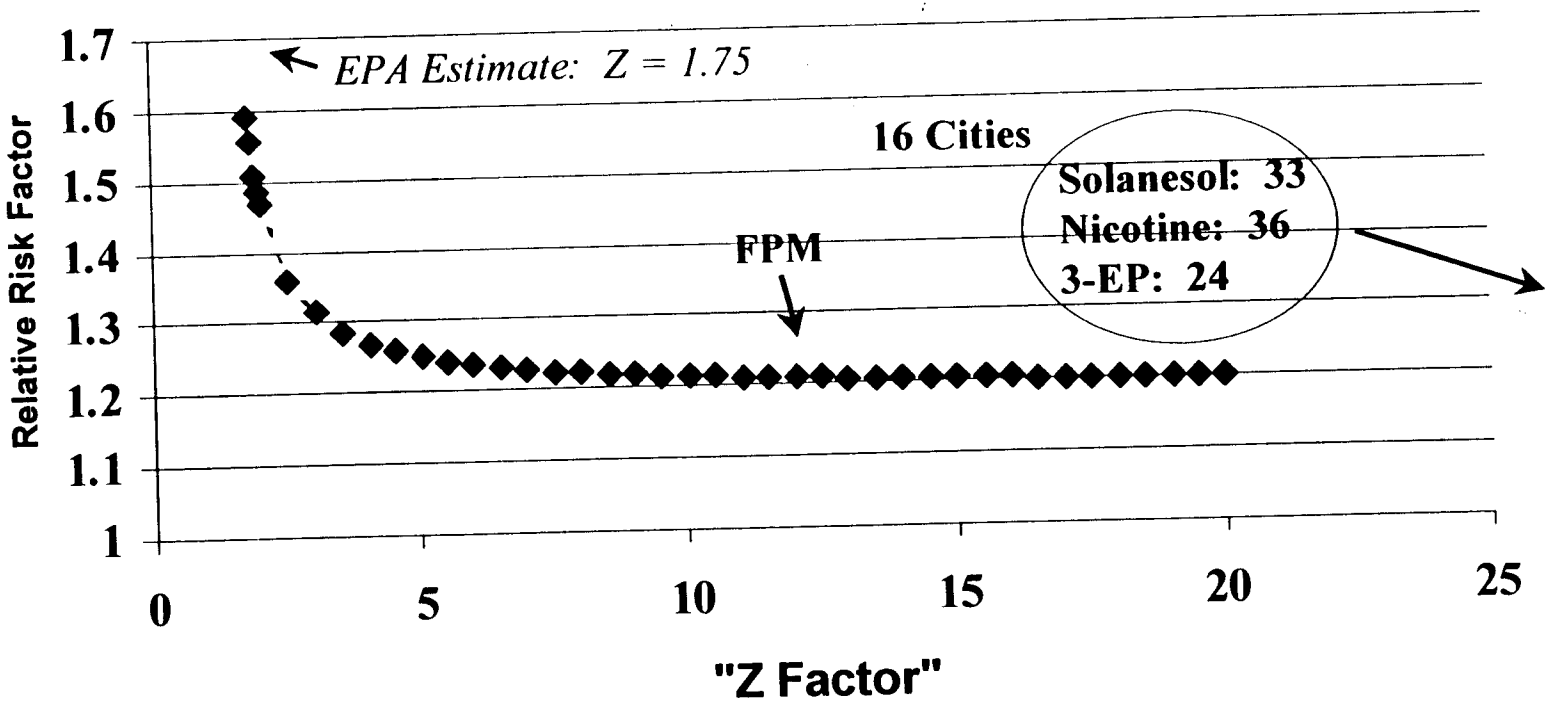
Married to Smokers vs. Married to Non-Smokers

Comparison of EPA Estimate with 16 Cities Data

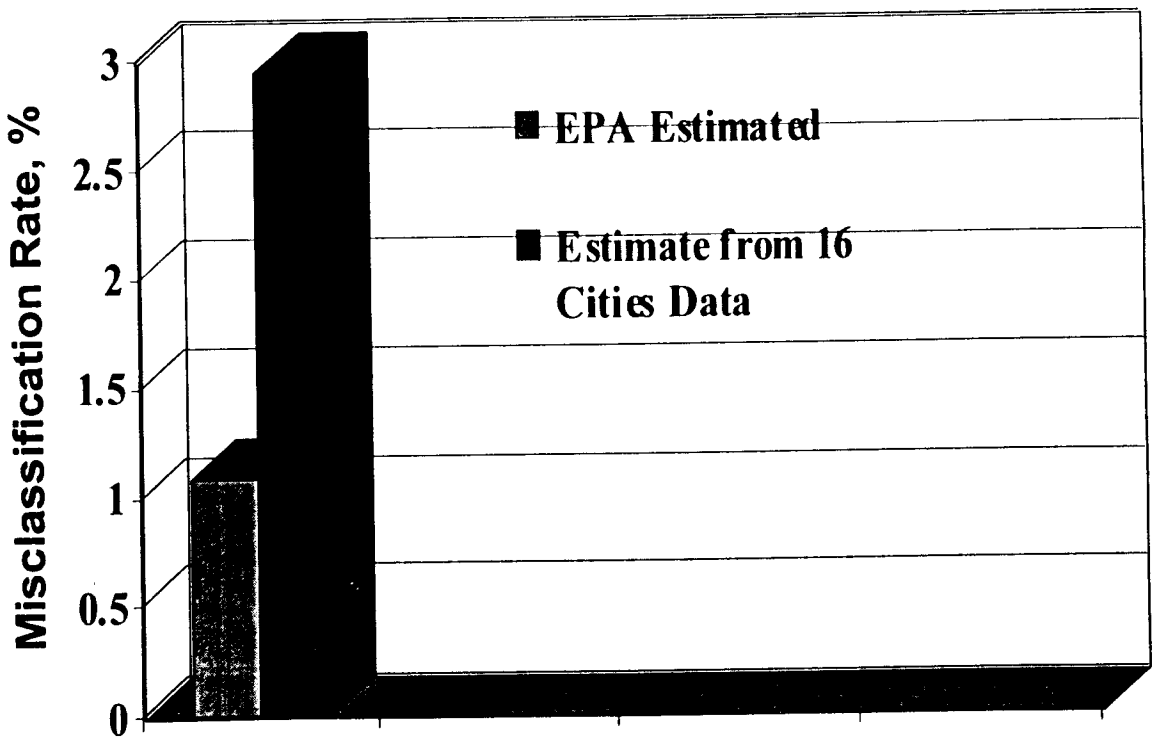


Impact of Differences in Z-Factor: EPA Estimate vs. ORNL 16 Cities Data

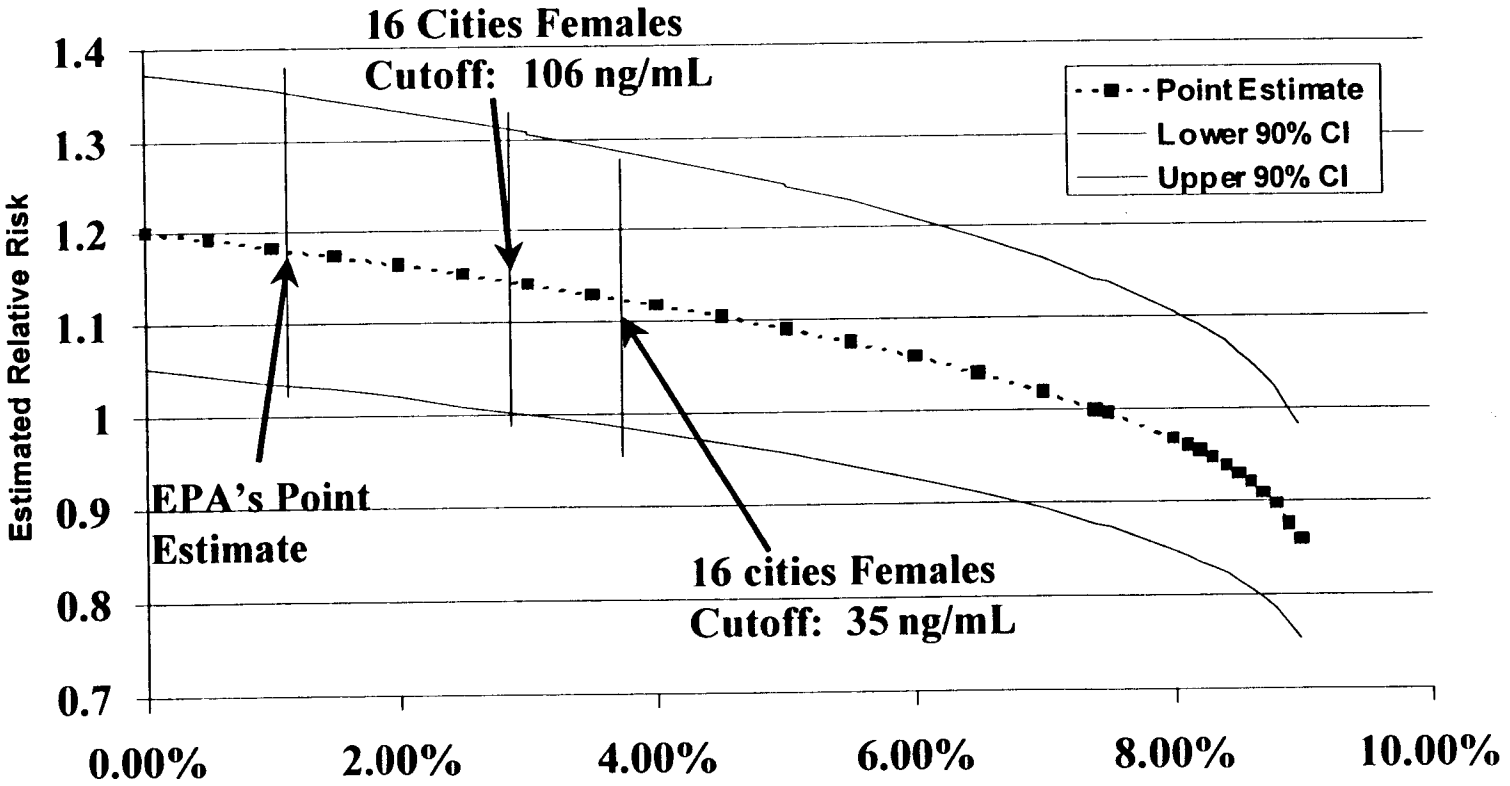
Z = Exposure ratio of women exposed from smoking spouse compared with women not exposed from spouse



Never Smoking Female Misclassification Rates: EPA Estimate vs. Data from 16 Cities Study



How "Never-Smoker" Misclassification Rates Impact EPA's Relative Risk Estimation



Conclusions

- Assumptions critical in EPA lung cancer risk assessment are not supported by 16 Cities data.
- Use of definitive data, rather than EPA estimates, would act to lower estimated Relative Risk.